



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/553,436	03/21/2006	Robert A. Macina	DEX0477US.NP	6995
32800	7590	08/28/2008	EXAMINER	
LICATA & TYRRELL P.C. 66 E. MAIN STREET MARLTON, NJ 08053			ZHOU, SHUBO	
			ART UNIT	PAPER NUMBER
			1631	
			NOTIFICATION DATE	DELIVERY MODE
			08/28/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

poreilly@licataandtyrrell.com

Office Action Summary	Application No. 10/553,436	Applicant(s) MACINA ET AL.	
	Examiner Shubo (Joe) Zhou	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 August 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 8-10 and 16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 8-10, and 16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Amendments

Applicants' amendments and request for reconsideration in the communication filed on 8/6/07 are acknowledged and the amendments entered.

Claims 1-5, 8-10, and 16 are currently pending and under consideration.

Inventorship

Applicant's request for amend the inventorship of the instant application to delete Albert Tam as an inventor due to the claim amendment is acknowledged and accepted. Inventorship has been changed.

Claim Rejections-35 USC §112

The following is a quotation of the **first** paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5, 8-10, and 16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for detecting risk or presence of colon cancer, lung cancer, in a human patient, does not reasonably provide enablement for detecting risk or presence of colon cancer, lung cancers in a patient other than humans, or detecting risk or presence of cancers in human patient for cancers other than colon cancer, lung cancer, such as prostate cancer. The

Art Unit: 1631

specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

This rejection is modified from the previous Office action.

In *In re Wands* (8 USPQ2d 1400 (CAFC 1988)), the CAFC considered the issue of enablement in molecular biology. The CAFC summarized eight factors to be considered in a determination of "undue experimentation". These factors include: (a) the quantity of experimentation; (b) the amount of guidance presented; (c) the presence or absence of working examples; (d) the nature of the invention; (e) the state of the prior art; (f) the predictability of the prior art; (g) the breadth of the claims; and (h) the relative skill in the art. The factors are analyzed for the instant case as follows:

In the instant case, the amount of experimentation required by the skilled artisan in order to practice detecting risk or presence of cancers other than colon cancer, lung cancer, such as prostate cancer would require an unpredictable amount of experimentation for the following reasons:

The claims are drawn to nucleic acid molecules or a kit comprising the same for detecting a risk or presence of cancer in a patient (see claim 16). The specification on pages 394-395 discloses that the expression of Cln224v1 is altered, over-expressed or down-expressed, in certain percentages of colon cancer samples and lung cancer samples compared to their adjacent normal tissues in humans, but there is no description in the specification that this nucleic acid of Cln224v1 is even expressed in a subject other than humans and/or its expression is altered in cancer samples of such subject compared to their adjacent normal tissues. Further, for cancers other than colon cancer and lung cancer, such as prostate cancer, in humans, there is no

Art Unit: 1631

description in the specification that the expression of Cln224v1 is altered in the cancer compared to its adjacent normal tissues so that it can be used as a marker for detecting risk or presence of the cancer. Similarly, the specification does not provide guidance, nor does it provide any working example, as to how to use such a nucleic acid molecule or kit comprising the same to detect the risk or presence of any cancer other than colon cancer and lung cancer such as leukemia in a patient.

The nature of the invention, i.e. a kit comprising a nucleic acid molecule for use to detect the risk or presence of a cancer in a patient, is complex. The prior art does not teach or fairly suggest such a kit. The skilled practitioner would first turn to the instant specification for guidance in practice of using the kit comprising the nucleic acid molecule comprising the sequence of SEQ ID NO:36 to detect the risk or presence of colon cancers or lung cancers in a patient other than a human patient such as an animal pet, or detecting the risk or presence of cancers in a human patient for any cancers other than colon cancer, lung cancer, such as prostate cancer or leukemia. However, the specification does not provide sufficient guidance or working example of practicing the invention. As such, the skilled practitioner would turn to the prior art for such guidance. However, the prior art does not teach such a kit. Finally, said practitioner would have to turn to trial and error experimentation for practicing using the claimed nucleic acid for detecting risk or presence of colon cancer, lung cancer in a patient other than humans, and cancers other than colon cancer, lung cancer, such as prostate cancer or leukemia in human s without adequate guidance from the specification or the prior art. Therefore, undue experimentation becomes the burden of the practitioner.

Applicant's arguments filed 8/6/07 have been fully considered but they are not persuasive. Applicant argues that the data shown on pages 391-395 of the specification demonstrate that Cln224v1 is altered in cancer tissue compared to normal tissues including breast, ovary, pancreas, small intestines, stomach and testes. This is not found persuasive because the data shown on those pages are inconsistent for these types of cancers. For example, for cancer of the ovary, the table on page 393 shows that there is no expression of the gene in many ovarian cancers and normal tissues. For cancer of the pancreas, only one of out 3 shows high in the tumor.

The following is a quotation of the **second** paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 16 is rejected under 35 U.S.C. 112 , second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 16 is written as including an apparent Markush group. However, it is an improper Markush claim and therefore the metes and bounds of the claim are not clear due to the use of the phrase "X is selected from the group comprising...." The proper form of a Markush group should recite members as being "X is selected from the group consisting of...and ...", or alternatively, "X is...or...". See MPEP 2173.05(h).

Provisional Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-6, 8-10, and 16 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6, 8-10, 16 and 18 of US compending Application No. 10/558861.

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claims because the examined claim is either anticipated by, or would have been obvious over, the reference claims. See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-6, 8-10, and 16 of the instant application are drawn to nucleic acid molecules comprising the sequence of SEQ ID NO:36 or any nucleic acid that encodes the polypeptide of SEQ ID N):194, which is encoded by SEQ ID NO:36, or any nucleic acids that hybridize selectively with any of the above under stringent conditions.

At least for one embodiment, 1-6, 8-10, 16 and 18 of US copending Application No. 10/558861 are drawn to nucleic acid molecules comprising the sequence of SEQ ID NO:52 or any nucleic acid that hybridizes selectively with the sequence of SEQ ID NO:52. Sequence comparison performed by the Office shows that the sequence of SEQ ID NO:52 of the copending application is identical to the SEQ ID NO:36 of the instant application. Thus, claims 1-6, 8-10, and 16 of the instant application are anticipated by claims 1-6, 8-10, 16 and 18 of the copending US application, respectively.

This rejection is reiterated from the previous Office action. In the response filed 8/6/07, applicant does not provide specific arguments against the rejection but argues that the instant application was filed earlier than 10/558861 and so it is the latter where a terminal disclaimer should be filed. This is not found persuasive because the examiner is rejecting the claims for double patenting not requesting filing a terminal disclaimer although the filing of which may overcome the rejection. Nevertheless, if the double patenting rejection is the only rejection left in the application, the application may go into allowance without a terminal disclaimer as it was filed earlier than 10/558861.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicants are reminded of the extension of time policy as set forth in 37 C.F.R. §1.136 (a). A shortened statutory period for response to this final action is set to expire three months from the date of this action. In the event a first response is filed within two months of the mailing date of this final action and the advisory action is not mailed until after the end of the three-month shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. §1.136 (a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than six months from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shubo (Joe) Zhou, whose telephone number is 571-272-0724. The examiner can normally be reached Monday-Friday from 8 A.M. to 4 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran, can be reached on 571-272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the

Art Unit: 1631

problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Shubo (Joe) Zhou/

SHUBO (JOE) ZHOU, PH.D.

PRIMARY EXAMINER